CABINET FOR HEALTH AND FAMILY SERVICES

Office of Health Policy

(Amendment)

900 KAR 6:120. Certificate of need angioplasty two year trial program [~~pilot projects~~].

RELATES TO: KRS 216B.010-216B.130, 216B.330-216B.339, 216B.990

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the Cabinet for Health and Family Services to administer Kentucky's certificate of need program and to promulgate administrative regulations as necessary for the program. This administrative regulation establishes the provisions for the certificate of need approved angioplasty two (2) year trial program [~~pilot project for primary angioplasty~~] in hospitals without on-site open heart surgery [~~("pilot program") established in the 2004-2006 State Health Plan for the certificate of need program~~].

Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(6)[~~(5)~~].

(2) "Days" means calendar days, unless otherwise specified.

(3) "Trial" means the certificate of need approved angioplasty two (2) year trial program in hospitals without on-site open heart surgery. [~~"Improvement" means change or addition to the premises of an existing facility that enhances its ability to deliver the services that it is authorized to offer under its existing license or an approved certificate of need.~~]

Section 2. [~~Pilot~~] Angioplasty Two (2) Year Trial Program. The provisions of this

section shall apply during the two (2) year period of the trial [~~to the pilot project~~] for primary (i.e. emergency) and elective angioplasty in hospitals without on-site open heart surgery [~~"pilot program" initially established in the 2004-2006 State Health Plan~~].

(1) Hospitals participating in the trial [~~pilot program~~] shall, within twenty-four (24) hours of the event or on the first business day following the event, report the following events to the Office of Health Policy by fax at (502) 564-0302 or by emailing the executive director:

(a) A death that occurs within twenty-four (24) hours of the cardiac catheterization procedure or hospital discharge. The report shall indicate if the death was a cardiac death or a noncardiac death.

1. A death shall be considered a cardiac death if the death was due to any of the following:

a. Acute myocardial infarction;

b. Cardiac perforation/pericardial tamponade;

c. Arrhythmia or conduction abnormality;

d. Cerebrovascular accident related to, or suspected of being related to, the cardiac catheterization procedure. An event shall be considered to be a cerebrovascular accident if there were acute neurological deficits recorded by clinical staff that persisted more than twenty-four (24) hours. The report shall note if these events occurred:

(i) During the index catheterization; or

(ii) During the index hospitalization;

e. Death due to complication of the procedure including bleeding, vascular repair, transfusion reaction, or bypass surgery; or

f. Any death in which a cardiac cause could not be excluded.

2. A death shall be considered a noncardiac death if the death was not due to cardiac causes as described in subparagraph 1 of this paragraph;

(b) Emergency coronary artery bypass graft surgery (CABG) within twenty-four (24) hours of the procedure or hospital discharge. An event shall be considered to be an emergency if there is a sudden and often life-threatening mishap that arises in the course of, and as a result of, the performance of a cardiac catheterization or angioplasty procedure. It shall not include patients either transferred directly from the cardiac catheterization procedure room or taken within twenty-four (24) hours to the operating room for surgical correction of emergent or life threatening cardiac disease; or

(c) Shock within twenty-four (24) hours of the procedure or hospital discharge.

(2) Hospitals participating in the trial [~~pilot program~~] shall report in writing within seven (7) days to the Office of Health Policy any of the following events:

(a) Cerebrovascular accident, which are acute neurological deficits recorded by clinical staff that persisted more than twenty-four (24) hours. The report shall note if these events occurred within thirty (30) days after the catheterization but were not clearly related to the procedure;

(b) Any intracranial bleed within thirty (30) days of the cardiac catheterization procedure;

(c) Recurrent Q wave or Non-Q wave myocardial infarction (MI) during the initial hospitalization; or

(d) Vascular complications which occur within twenty-four (24) hours of the cardiac catheterization procedure or hospital discharge. These shall include:

1. Hematoma of more than four (4) centimeters;

2. Retroperitoneal Bleed;

3. False Aneurysm;

4. AV fistula;

5. Peripheral ischemic/nerve injury; or

6. Hemolysis and Hemolytic anemia.

(3) Hospitals participating in the trial [~~pilot program~~] shall:

(a) Establish a Joint Performance Improvement Committee (Joint PI Committee) with its collaborating tertiary hospital or with practicing interventional cardiologists. The membership of the Joint PI Committee shall, at a minimum, include each of the following disciplines from both the [~~pilot program~~] hospital participating in the trial and the collaborating tertiary hospital:

1. Physicians;

2. Nurses; and

3. Administrators;

(b) Convene the Joint PI Committee at least quarterly but sooner if twenty-five (25) patients have been treated to review the care provided to patients under the trial [~~pilot program~~]. This review process shall focus on patient outcomes and, at a minimum, include:

1. An assessment of the appropriateness of the selection of each patient entered into the trial [~~pilot program~~];

2. All complications, any adverse outcomes, and for transfers, the number of patients requiring transfer and the reason for each transfer to a tertiary facility;

3. The technical quality of the catheterization and angioplasty procedures performed; and

4. The "door to cath lab time" and "door to treatment time";

(c) Develop and implement a plan of correction for any problems identified;

(d) Develop a process for including the findings of the Joint PI Committee's review in the trial [~~pilot program~~] hospital's performance improvement program; and

(e) [~~Require the Joint PI Committee to make a quarterly recommendation to the Office of Health Policy whether the pilot program should continue; and~~

~~(f)~~]Require all staff, including interventional cardiologists, nurses, and technicians, as well as representatives of the Emergency Department and Critical Care Unit staffs participating in the trial performance improvement [~~pilot program PI~~] process, to attend a minimum of one (1) meeting of the Joint PI Committee per year.

(4) Performance of primary and elective angioplasty at a hospital as measured by quality indicators including mortality, morbidity, and adverse reactions shall be comparable, on a risk adjusted basis, to the performance of existing angioplasty programs in Kentucky and with similar organizations nationally, according to the National Cardiovascular Data Registry.

(a) If the outcomes are worse at a [~~pilot~~] hospital participating in the trial, that facility shall file and implement a plan of correction with the Office of Health Policy.

(b) If the facility's results do not improve after one (1) quarter of implementing a plan of correction, the Office of Health Policy may terminate the facility's participation in the trial [~~pilot program~~].

(5) Hospitals participating in the trial [~~pilot program~~] shall:

(a) Continue to make available the primary angioplasty [~~cardiac catheterization~~] service twenty-four (24) hours per day and seven (7) days per week;

(b) Develop policies and procedures that will assure that all interventional cardiologists performing [~~primary~~] angioplasty procedures at the [~~pilot program~~] hospital participating in the trial maintain an appropriate level of proficiency as a member of the team performing [~~primary~~] angioplasty at the [~~pilot program~~] hospital participating in the trial]. The policies and procedures shall detail the process the physician director will utilize to assure the establishment, maintenance, and monitoring of the proficiency of each interventional cardiologist; and

(c) Maintain a collaborative association and a current, valid collaboration agreement with a tertiary hospital including Joint PI and staff education programs. [~~; and~~

~~(d) Perform a minimum of thirty-six (36) primary angioplasty procedures per year. At least thirty (30) of these angioplasty procedures shall be primary angioplasty procedures, excluding patients that have "rescue angioplasty" procedures performed.~~

~~(6) The time frame for measuring compliance with procedural utilization requirements shall begin six (6) months after the date of the physician director's notification to the Office of Health Policy that all training requirements have been fulfilled. Within twelve (12) months from the start date, the hospital shall have performed eighteen (18) primary angioplasty procedures or shall receive a warning that approval to participate in the pilot program may be withdrawn.~~

~~(7) Within the following six (6) months, a total of eighteen (18) months from the date of the department's letter of approval, the hospital shall have performed at least another eighteen (18) procedures for a total of thirty-six (36) primary angioplasty procedures, or~~

~~the program may be discontinued at that site.~~

~~(8) Each site shall continue to perform at least eighteen (18) primary angioplasty procedures per six (6) months and a total of thirty-six (36) primary angioplasty procedures per year, or the program may be discontinued at that site.~~]

(6) [~~(9)~~] All physicians performing angioplasty procedures [~~percutaneous coronary intervention (PCI)~~] at a [~~pilot program~~] hospital participating in the trial shall:

(a) Continue to perform no fewer than 75 angioplasties [~~100 cardiac catheterization diagnostic and therapeutic procedures~~] per year. [~~At least seventy-five (75) procedures shall be angioplasty procedures unless the procedures are being performed at a facility at which more than 400 angioplasty procedures are being performed per year~~]; and

(b) Be board certified by the American Board of Internal Medicine in interventional cardiology. [~~Maintain credentials at a hospital at which that operator performs elective angioplasty procedures.~~]

(7)(a) [~~(10)(a)~~] All staff that are hired after the completion of the initial training at the [~~pilot program~~] hospital participating in the trial shall complete a training program that mirrors the initial training program. The hospital participating in the trial and its [~~relevant~~] collaborating tertiary hospital [~~and pilot program hospitals~~] shall develop this training program.

(b) Training of all staff including all interventional cardiologists, nurses, and technicians, shall be performed on the intra-aortic balloon pump annually.

(c) All staff involved in providing PCI, including the interventional cardiologists, nurses and technicians, shall have a current Advanced Cardiac Life Support (ACLS) certification.

(d) Inservice programs shall be based upon need identified through staff evaluations and the quality assurance process.

(8) [~~(11)~~] The Office of Health Policy may discontinue the trial [~~pilot program~~] at a participant hospital at any time after reviewing the following:

(a) Quarterly reports made by the American College of Cardiology - National Cardiovascular Data Registry (ACC-NCDR);

(b) Records obtained through an audit; or

(c) Patient medical records. [~~Peer review reports; or~~

~~(d) Reports on serious adverse events.~~]

(9) [~~(12)~~] Upon notification to the hospital by the Office of Health Policy, the hospital shall terminate the trial [~~pilot program~~] and cease to perform [~~primary~~] angioplasty procedures.

(10) [~~(13)~~] In order to assist the Office of Health Policy in evaluating the trial [~~pilot~~] program, the performance of [~~pilot~~] hospitals participating in the trial, and the formulation of recommendations for continuing or modifying the trial program [~~project~~], the Office of Health Policy may collaborate with university based researchers to:

(a) Evaluate and compare performance data of [~~pilot~~] hospitals participating in the trial with existing Kentucky angioplasty programs; and

(b) Conduct an evaluation of the short-and long-term outcomes of patients undergoing [~~primary~~] angioplasty at [~~pilot~~] hospitals participating in the trial with those patients transferred to hospitals with open heart surgical backup.

[~~(14) The Office of Health Policy shall review reports from the collaborating university based researchers as well as quarterly reports made by the ACC-NCDR,~~

~~records obtained through audit, peer review reports, and reports of serious adverse events in order to develop recommendations for continuing, discontinuing, or modifying the pilot program. If the project is continued, these recommendations shall include establishing criteria for determining need to expand angioplasty services to additional hospitals without on-site surgical backup, qualifications of those hospitals, and ongoing requirements for a hospital's continued provision of this service.~~]

(11) [~~(15)~~] The Office of Health Policy may convene all hospitals participating in the trial [~~pilot program~~] on a regular basis for the purpose of discussing and assessing the trial [~~status of the implementation of the pilot~~] program.

[~~(16) Three (3) years from the start date of the pilot program, the Office of Health Policy shall publish a report on the program that shall:~~

~~(a) Indicate whether it is in the best interest of the Commonwealth to eliminate the requirement for open heart surgery for hospitals to perform therapeutic cardiac catheterization; and~~

~~(b) Include the requirements for patient selection, procedural volume, and staffing that hospitals shall continue to meet if the Office of Health Policy finds that this service may be provided by hospitals in the absence of on-site open heart surgery.~~ (36 Ky.R. 257; Am. 818; eff. 10-21-09.)

900 KAR 6:120

APPROVED:

Emily Whelan Parento
Executive Director
Office of Health Policy

5/29/13
Date

APPROVED:

Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services

6/4/13
Date

900 KAR 6:120
PUBLIC HEARING AND COMMENTS:

A public hearing on this administrative regulation shall, if requested, be held on July 22, 2013, at 9:00 a.m. in the Auditorium A, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by July 15, 2013, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until July 31, 2013. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:120
Contact Person: Diona Mullins (502) 564-9592

1. Provide a brief summary of:

   (a) What this administrative regulation does: This administrative regulation establishes the provisions for the certificate of need approved angioplasty two (2) year trial program in hospitals without on-site open heart surgery.
   (b) The necessity of this administrative regulation: KRS 216B.040(2)(a)1 requires the cabinet to administer the certificate of need program and to promulgate administrative regulations as necessary for the program.
   (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the requirements for a certificate of need approved angioplasty two (2) year trial program.
   (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The amendment of the regulation will assist certificate of need holders and applicants by providing the requirements for participation in the two (2) year angioplasty trial program.

2. If this is an amendment to an existing administrative regulation, provide a brief summary of:

   (a) How the amendment will change this existing administrative regulation: The amendment will address the requirements for participation in the certificate of need angioplasty trial program which has recently been expanded to include elective angioplasty.
   (b) The necessity of the amendment to this administrative regulation: The amendment to this regulation will conform to the requirements of the certificate of need angioplasty trial program established in the State Health Plan, 900 KAR 5:020. The trial has recently been expanded to include elective angioplasty.
   (c) How the amendment conforms to the content of the authorizing statutes: KRS 216B.040(2)(a)1 requires the cabinet to administer the certificate of need program and to promulgate administrative regulations as necessary for the program.
   (d) How the amendment will assist in the effective administration of the statutes: This amendment will provide the requirements for participation in the certificate of need approved angioplasty two (2) year trial programs in hospitals without on-site open heart surgery.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect six (6) hospitals which currently have outstanding certificates of need for the angioplasty trial program as well any additional hospital that receives certificate of need approval for the trial program.

4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

   (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Certificate of need approved angioplasty trial programs shall comply with the performance improvement and reporting requirements of this amendment during the two (2) year trial program.

   (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Applicants proposing to establish a trial angioplasty program will be required to submit an additional $10,000.00 certificate of need application fee as established in 900 KAR 6:020. Certificate of need holders will be required to report specific events to the Office of Health Policy and participate in a performance improvement program during the trial program. At the conclusion of the trial, a hospital is required to have an outside consultant verify that the quality of the program's risk-adjusted statistics are acceptable.

   (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): A hospital that successfully completes the trial in accordance with this regulation shall have the trial status removed from its certificate of need.

5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

   (a) Initially: Up to $10,000 per trial.
   (b) On a continuing basis: Up to $10,000 per trial.

6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The certificate of need application fee for angioplasty trial programs includes an additional fee of $10,000 pursuant to 900 KAR 6:020.

7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.

8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.

9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6: 120 Contact Person: Diona Mullins

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned hospitals.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.040(2)(a)1 requires the Cabinet for Health and Family Services to administer Kentucky's Certificate of Need Program and to promulgate administrative regulations as necessary for the program.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? $10,000 revenue for the Office of Health Policy per CON applicant is anticipated during the first full year. The number of hospitals that will apply for CON during the first year is unknown.

   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? $10,000 per CON application filed.

   (c) How much will it cost to administer this program for the first year? None of the 6 participating hospitals will complete the trial during the first year. Estimated that it will cost the Cabinet up to $10,000 per trial, with the majority of funds be expended during the second year of the trial.

   (d) How much will it cost to administer this program for subsequent years? Up to $10,000 per facility completing the trial.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):
Expenditures (+/-):
Other Explanation: